

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY)	MDL NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	CIVIL ACTION: 01-CV-12257-PBS
)	Subcategory Docket: 06-CV-11337-PBS
)	
THIS DOCUMENT RELATES TO)	Judge Patti B. Saris
)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc., et al., No.</i>)	
07-CV-11618-PBS)	
)	

**ABBOTT LABORATORIES INC.'S REPLY MEMORANDUM IN SUPPORT
OF ITS MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS
PROFFERED BY PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D.**

Dated: December 4, 2009

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INTRODUCTION

Dr. Duggan's "difference" calculations in this case are flawed for reasons in addition to those that will be presented to this Court at the December 10-11, 2009 *Daubert* hearing on Dr. Duggan's extrapolations in the United States intervened case against Abbott. Here, Duggan admits that he did not consider (1) whether Medicaid payments for Abbott's Ery drugs were based on FULs, MACs, U&Cs or any other number, (2) whether the published prices for the Ery drugs had any impact on the FULs and MACs set for erythromycin, and (3) whether there is any evidence that anyone (besides Ven-A-Care) believed that payments based on FULs or MACs constituted fraudulent overpayments at all. At bottom, then, neither Duggan nor Ven-A-Care has presented any evidence to show – and, more important for purposes of this motion, to quantify – how, if at all, reported prices for Abbott's Ery drugs caused inflated Medicaid payments. Duggan's omissions – coupled with the total lack of evidence on the critical issue – renders Duggan's simplistic "difference" calculations irrelevant, unusable, and inadmissible as a measure of damages in this case. Moreover, his entire exercise ignores the reality that Ven-A-Care's theory that Abbott marketed the spread on the Ery drugs makes no sense because reporting inflated prices would have been futile when the Medicaid payments were capped by FULs and MACs.

To make matters worse, Duggan again used extrapolations, from limited periods of data from less than a third of the Medicaid states, which are unmoored to any accepted scientific standard. Contrary to Ven-A-Care's suggestion, the *Daubert* rule has no "too big to fail" exception and should not, particularly when the absence of data is entirely the plaintiff's fault and the plaintiff is seeking punitive treble damages.

The Court, fulfilling its critical role of gate keeper, must look past Dr. Duggan's resume to the paucity of his analysis and exclude his opinions. There simply is no precedent for admitting Duggan's flawed theory and unscientific extrapolations.

ARGUMENT

I. DUGGAN'S "DIFFERENCES" CALCULATIONS SHOULD BE EXCLUDED IN ITS ENTIRETY DUE TO HIS FAILURE TO TETHER HIS COMPUTATIONS TO THE ACTUAL IMPACT (IF ANY) OF ABBOTT'S PRICES ON MEDICAID PAYMENTS.

Ven-A-Care alleges that Abbott's published prices "directly influenced" the "reimbursement amounts paid [by] the Medicaid programs." (Complaint ¶ 39.) Duggan's admission that he did nothing to substantiate this allegation – to provide the link between Abbott's published price and the amounts paid by the State Medicaid programs – renders his opinions inadmissible under the *Daubert* standard. Ven-A-Care bears the burden of proving that Duggan's opinions rest on a reliable foundation and are relevant to the task at hand. *McGovern v. Brigham & Women's Hospital*, 584 F. Supp. 2d 418, 423 (D. Mass 2008). "The first step of a *Daubert* inquiry pertains to relevance: to be admissible, an expert's testimony must have a 'valid . . . connection to the pertinent inquiry.'" *Id.* (citations omitted.) Because Dr. Duggan did not consider whether Abbott's published prices had any impact on the Medicaid payments to pharmacists, his "differences" analysis simply does not support Ven-A-Care's allegations and is irrelevant to the case.

Most of the claims for which Duggan computes a "difference" were based not on the compendia prices about which Ven-A-Care complains, but on a FUL, MAC or U&C charge. (SOF ¶¶ 71, 87, 88, 111.) Ven-A-Care does not and cannot rebut this inescapable fact. This Court has consistently ruled in AWP litigation that, to recover damages for claims involving multi-source drugs, plaintiffs must show that the payments were, in fact, based upon or at least

directly influenced by a published price at issue. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 180 (D. Mass 2007); *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 230 F.R.D. 61, 91 (D. Mass 2005); *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 151 (D. Mass 2008). Duggan’s \$15,559,108 “difference” opinion, which glosses over this requisite proof, is inconsistent with this Court’s previous rulings and cannot serve as a relevant or reliable measure of damages in this case.

Duggan concedes that he did not even attempt to prove that the damages sought are derived from payments based on the published Ery prices at issue. Although he acknowledges that his calculations for Medicaid claims included “differences” for claims that were, in fact, based on FULs and MACs, Duggan confesses in his report that “[i]t is worth noting that *I have not evaluated the effect of Abbott’s published prices on the calculation of FUL or MAC prices.*” (Berlin Ex. 95, Duggan Ery Report at 27, n.19 (emphasis added); *see also* Berlin Ex. 97, 4/17/09 Duggan Ery Dep. at 119:5-120:2, 120:22-121:10, 123:10; 123:6-124:8 (“[A]s I outline in my report, I do not account for the effect of a transaction-based AWP on the MACs or FUL prices. And [] it was not the focus of my analysis to determine the method that each state used in determining MAC prices.”).) Despite his decision to include “differences” for claims paid based on FULs or MACs, Duggan fails to present any evidence (or even speculation) that an Abbott reported price impacted a FUL or MAC or any Medicaid payment. These concessions alone render his “difference” computation inadmissible.

Nevertheless, Ven-A-Care continues to profess – wholly without support – that Abbott’s published “prices were utilized by state Medicaid agencies to calculate drug reimbursement amounts.” (Resp at 1.) Even where that is true for some small percentage of the claims, that is irrelevant to this motion for two reasons. First, the fundamental problem is that Duggan’s proposed “difference” opinion does nothing to separate the wheat (claim where Abbott’s “prices

were utilized by state Medicaid agencies to calculate drug reimbursement amounts” (*id.*)) from the chafe (claims not paid based upon Abbott’s prices). It is therefore unusable and irrelevant. Second, neither Ven-A-Care nor Duggan has shown, or (after almost 15 years of discovery and investigation) collected any evidence to show, that any of the MACs or FULs at issue here were actually based on or in any way influenced by Abbott’s reported prices – as opposed to other manufacturers’ prices or prices obtained from wholesalers or set due to independent policy concerns. (SOF ¶¶ 89-92.)¹

Ven-A-Care goes to great lengths in its futile attempt to distinguish this Court’s previous opinion in the California AWP litigation. In that case, this Court dismissed the complaint “as it relate[d] to the drugs reimbursed on a MAIC methodology”² because there was no causal link between the MAC prices and the allegedly false prices reported by defendants. *In Re Pharmaceutical Industry Average Wholesale Price Litig.*, 478 F. Supp. 2d at 180. The Court did so because California – like many other states – used information from wholesalers to set their state MACs, not compendia prices. *Id.*

Unable to distinguish this holding from the pertinent question here, Ven-A-Care tries to avoid the holding’s impact on this motion by advancing two erroneous contentions and a misleading use of a declaration from Kevin Gorospe of California Medicaid. Ven-A-Care’s first contention, that “California did not normally place” MACs on Erys (Resp. at 3), finds no support in Mr. Gorospe’s declaration and is, in fact, contradicted by the record. According to documents produced by the State of California, MACs were in place as early as 1995 for certain Ery drugs.

¹ Ven-A-Care’s citation to *United States ex. rel Tyson v. Amerigroup Illinois, Inc.*, for the proposition that “failure to include all possible factors in a reasonable estimation of damages is not fatal” is inapposite and easily distinguishable. The expert criticized in *Tyson* failed to account for some variables in his analysis; here, Duggan failed to consider the factor – whether the reported Ery price in fact caused the allegedly inflated Medicaid payment. 488 F. Supp. 2d 719, 733 (N.D. Ill. 2007).

² Although California referred to its state mandated maximum allowable costs as “MAICs,” the term “MAC” is used here for consistency.

(Berlin II Ex. 9, Collection of California MAIC Lists.) Ven-A-Care's second contention, that "California Medicaid typically paid using a lower of formula comparing FULs, which were lower than the California-specific [MACs] and EACs" is misleading, easily contradicted, and irrelevant here. A brief review of the MAC lists in place during the relevant time period reveals that several of the MACs in place for Erys were lower than the FULs. (Berlin II Ex. 9.) And it would not matter if payments were based on a FUL anyway, since neither Duggan nor Ven-A-Care has made any showing that Abbott's reported price had any impact on those FULs. In other words, Ven-A-Care has not advanced a "FUL fraud" case akin to what this Court has seen in the New York Counties litigation.

The California Medicaid payments for Erys were based on MACs, and the Court's dismissal of those claims applies here. This is not surprising, in light of the fact that eleven of the Ery NDCs at issue in this case were included (and dismissed) in the California AWP litigation. Because it has not made any showing of "FUL fraud," Ven-A-Care has no other option but to resurrect its already rejected theory that, had Abbott reported lower prices, those lower prices would have formed the basis of payment for states which used a lower-of methodology. Apart from the fact that this argument has already been rejected, 478 F. Supp. 2d at 180, Ven-A-Care completely ignores the absurdity of its theory when applied to its factually unsupported allegations of marketing the spread. Simply put, Abbott could not and did not increase its market share by manipulating Medicaid payment over which it had no control. As this Court has recognized, Abbott could not market the spread where the payment was capped. *See In Re Pharm. Industry Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 24-25 (D. Mass 2007) ([Abbott] has the better argument that mere publication of a false AWP, without more, does not constitute an offer of remuneration where reimbursement is based on a median of AWPs, as it is with Abbott's multi-source drugs."); *see also Mylan* 608 F. Supp. 2d at 151

(noting Massachusetts also used FULs and MACs for generics and stating plaintiffs failed to show how defendants' reported prices actually "formed the basis for the drugs FUL and MUL.".)³ Duggan's "difference" opinion runs contrary to this Court's well reasoned prior decision and should be stricken on that basis.

II. DUGGAN'S EXTRAPOLATIONS ARE NOT BASED ON REPRESENTATIVE SAMPLES AND ARE INCONSISTENT WITH GOVERNING STANDARDS.

Duggan's extrapolation methods are unacceptable in theory and unreliable in application. An expert's testimony which does not result from applying reliable principles and methods to the facts of the case is inadmissible. Fed. R. Evid. 702. The factors used to evaluate the admissibility of expert testimony include: (1) whether the theory or technique can be and has been tested; (2) whether the technique has been subjected to peer review and publication; (3) the technique's known or potential rate of error; (4) the existence of standards controlling the technique's operation; and (5) the level of the theory's or technique's acceptance within the relevant discipline. *U.S. ex. rel. Loughren v. Unumprovident Corp.*, 604 F. Supp. 2d 259, 264 (D. Mass 2009). Because Ven-A-Care has failed to show that Duggan's "non-traditional" methods have been tested or subjected to peer review, employed any controlling standards (apart from Duggan's judgment calls), or produced results with an acceptable rate of error (as opposed to the absurd results that they do produce), Duggan's resulting opinions must be excluded.

Instead of analyzing the entire universe of state Medicaid claims data, Duggan extrapolated "differences" from 15 states (using incomplete sets of data) to 34 states (with no state claims data at all). Duggan's extrapolations account for over half (\$8,491,936) of the \$15,559,108 in Medicaid damages claimed by Ven-A-Care. While courts have sanctioned the use of extrapolation, they have universally required the use of a statistically valid, representative

³ Ven-A-Care's own marketing expert, Matthew Perri, conceded this. (5/1/09 Perri Dep. at 85:7-86:17; 103:17-104:1, Berlin II Exhibit 10.)

sample. *See Loughren*, 604 F. Supp. 2d at 261 (“extrapolation is a reasonable method . . . so long as the statistical methodology is appropriate”) (citing cases). The root problem with Duggan’s analysis is his admitted failure to use a representative sample of the allegedly false claims at issue. Ven-A-Care admits that its expert “did not use a traditional random sample.” (Resp. at 3.) Instead of creating a random sample, Duggan resorted to biased “convenience samples” focused on high-expenditure states.

Duggan’s purported “samples” of 7.8 million claims are not, in fact, “samples” of anything. A sample is a “*subset of the population that is used to gain information about the entire population,*” or a “*method of selecting a fraction of the population in a way that the selected sample represents the population.*” *Utah v. Evans*, 536 U.S. 452, 467-68 (2002) (emphasis added) (citing G. Henry, *Practical Sampling* 11 (1990); P. Sukhatme, *Sampling Theory of Surveys with Applications* (1954)). Duggan admits that the “typical way to select a representative, non-biased sample is through randomization.” (Duggan Decl. at ¶ 51.) Duggan further admits, however, that the claims he studied were not “subsets” of the entire population of allegedly false claims. Rather, they are the entirety of the claims data provided by the plaintiffs for a minority of states, which Duggan must concede are not themselves representative of other states. (Duggan Decl. at ¶ 12.)

Duggan’s “samples” are not valid because they are not drawn from “the population [of] the whole class of units that are of interest” – claims from *all* states, *all* carriers, and *all* time periods – such that each claim had a “known, nonzero probability of being chosen.” *Reference Manual on Scientific Evidence* at 90, 100. Due to the variation in how states and carriers paid for the Subject Drugs, “samples” that omit claims from 34 states entirely and omit years of claims from others cannot possibly be representative. *See id.* at 90 (“[T]he population is the whole class of units that are of interest; the sample is a set of units chosen for detailed study. Inferences from

the part to the whole are justified only when the sample is representative.”). In statistic jargon, his “samples” are under-inclusive.

Ven-A-Care’s citation to page 244 of the *Reference Manual* (Resp. at 12) is inapposite. Page 244 concerns the irrelevant context of consumer *surveys*. Even there, the *Reference Manual* and case law recognize that issues associated with using non-representative samples may render the survey results inadmissible. *See id.* at 231, 241-43; *Chavez v. IBP, Inc.*, No. CV-01-5093-RHW, 2004 WL 5520002, at *8-9 (E.D. Wash. Dec. 8, 2004) (excluding survey not based on random, probability sample). By contrast, the standards cited by Abbott, such as CMS’s own Transmittal B-03-022, *Use of Statistical Sampling for Overpayment Estimation When Performing Administrative Reviews of Part B Claims*, are directly on point. Ven-A-Care admits that Duggan’s extrapolations do not meet the standards articulated by CMS, and instead urges the Court simply to ignore CMS’s own guidance on the topic. This the Court should not do, particularly in a case where Ven-A-Care seeks to treble any damages computed through Duggan’s flawed extrapolation. (*See* Abt. Br. at 8, n. 8.)

At bottom, the methodologies challenged here involve the extrapolation of findings from a non-random, non-representative set of claims to another collection of claims processed either by a different set of states and carriers or at different times. Neither Abbott nor Ven-A-Care has identified a single case allowing an expert to present the sort of extrapolations employed here.

The problems with Duggan’s analysis are much like the flaws in the expert report discarded by this Court earlier this year in *U.S. v. Loughren v. Unumprovident Corp.*, 604 F. Supp. 2d 259 (D. Mass 2009). As Duggan did, the *Loughren* expert considered and rejected the use of simple random or stratified sampling, and instead extrapolated his findings from “cohort samples” which he believed was “the most efficient and suitable approach.” Duggan, too, criticized the use of a full data set as “often time-consuming or prohibitive or unnecessary.”

(Duggan Dec. ¶ 34.) The court struck the *Loughren* expert report for two reasons. First, the *Loughren* plaintiff failed to establish that its expert’s method of extrapolation had been “subject to peer review and publication, or has gained acceptance within the relevant discipline.” 604 F. Supp. 2d at 266, 269. Abbott has been unable to locate any precedent in law or literature which would support the “sample of convenience” approach taken by Duggan. Second, the *Loughren* defendant “presented convincing evidence that the technique is susceptible to manipulation and significant error.” *Id.* at 269. Abbott’s brief demonstrated that Duggan’s failure to adhere to statistical standards, coupled with significant variability in how states paid for the Erys, led to absurd results akin to what this Court saw in *Loughren*. (Abt. Br. at 17-20.)

Ven-A-Care does not dispute that Duggan’s extrapolations led to clearly erroneous results. The examples cited in Abbott’s brief, which prove the unreliability of Duggan’s extrapolations, include situations where Duggan’s approach led to states paying negative amounts in ingredient reimbursement. Unable to defend the conclusions reached by its expert, Ven-A-Care suggests – without empirical, logical or legal support – that these examples are “biased unrepresentative anomalies,” which are properly addressed during cross examination of Duggan at trial. The deficiencies in Duggan’s inter-state extrapolation stem from Duggan’s systematic failure to determine which states established MACs for the Erys or to compare the relative prevalence (or numerical values) of state MACs among the 15 and 34 state groups, respectively. (Abt. Br. at 16.) The examples of absurd results are not “cherry-picked,” but rather are symptomatic of why Duggan’s failure to use representative samples renders his extrapolations unreliable. Duggan’s intra-state extrapolation is also unreliable, particularly with respect to payments made on the basis of U&C. (Abt. Br. at 19-20.) It is Ven-A-Care, not Abbott, who has the burden to provide empirical evidence to show that Duggan’s approach is, in fact, “accurate when implemented across the board.” Ven-A-Care is in the same position as the

plaintiff in *Loughren*, with its expert unable to “explain how it is possible that his method could result in such a patently wrong answer.” *Loughren*, 604 F. Supp. at 268.

Remarkably, Ven-A-Care criticizes Abbott’s experts for failing to quantify Duggan’s errors. (VAC Resp. at 15-16.) The burden to establish the reliability of Duggan’s testimony rests squarely on Ven-A-Care, not on Abbott or its experts. *See Loughren*, 604 F. Supp. 2d at 264; *Alexian Bros. Health Providers Ass’n, Inc. v. Humana Health Plan, Inc.*, 608 F. Supp. 2d 1018, 1027 (N.D. Ill. 2009); *Reynolds v. Giuliani*, 118 F. Supp. 2d 352, 367 (S.D.N.Y. 2000) (“The City defendants, as the proponents of the audit, bear the burden of assuring that the results lack statistical bias. In this Court’s view, they have not done so. Once plaintiffs had thoroughly undermined the structuring underpinnings of the Reynolds Audit, they were not required to identify the direction in which it would topple.”). This is particularly true here, where Duggan ignored well-established standards governing the use of extrapolation, and did not present this Court with any sort of confidence interval to assess the reliability of his extrapolations. Any quantification would have to grapple with the erroneous premise of Dr. Duggan’s methodology.

As is often the case when a party proffers unsound expert testimony, Ven-A-Care asks the Court to ignore the fundamental shortcomings of Duggan’s methodologies and leave those issues for cross-examination at trial. The Court should reject that plea, as the “*Daubert-Kuhmo* canon teach[es] that the critical issue is the soundness of [the expert’s] methodology, for only such soundness provides a reasonable assurance that the GIGO (‘garbage in, garbage out’) hazard has been avoided.” *Alexian Bros.*, 608 F. Supp. 2d at 1027. Even without addressing the extrapolated aspects of Duggan’s opinions, cross-examination of Duggan will be extensive and complicated. It is not the jury’s role to learn and decipher the complex statistical issues that surround Duggan’s extrapolations. They will have enough to do in this complicated trial. The Court’s “vigilant exercise” of its “gate-keeper role is critical,” and the cracks in the structural

underpinnings of Duggan's extrapolation methodologies are precisely why the Court should exclude the proffered testimony. *Loughren*, 604 F. Supp. 2d at 264 ("An expert's methodology is the 'central focus of a *Daubert* inquiry.'").

CONCLUSION

For the foregoing reasons, the Court should enter an order excluding Duggan from offering any testimony regarding the "difference" between what Medicaid programs paid for the Erys and what they allegedly "would have paid" had Abbott reported different prices.

Dated: December 4, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Tara A. Fumerton, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY PLAINTIFF'S EXPERT MARK G. DUGGAN, PH.D. to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 4th day of December, 2009.

/s/ Tara A. Fumerton
Tara A. Fumerton